INDEPENDENT REVIEWERS OF TEXAS, INC.

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Notice of Independent Review Decision

Date notice sent to all parties:
August 27, 2012 and August 28, 2012

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
Appeal C4-5-6 Revision, Hardware Removal, C6-7 ACDF w/Instrumentation 1 Day LOS

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:
Board Certified Orthopedic Surgeon

REVIEW OUTCOME:
Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:
☐ x Upheld (Agree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

1. Operative report 08/06/08
2. Clinical notes 01/06/10-06/03/10
3. Evaluation 06/15/10
4. Pain management note 07/07/10
5. Clinical note 07/28/10
6. Clinical note interventional pain management note 08/11/10 and 09/15/10
7. Clinical note 09/16/10
8. Interventional pain management note 11/09/10
9. Clinical note 12/14/10
10. Clinical note
11. Interventional pain management report 01/17/11
12. Clinical note 01/19/11
13. Interventional pain management report 02/16/11
14. Clinical note 03/14/11
15. Interventional pain management notes 03/16/11 and 04/25/11
16. Clinical note 04/26/11
17. Clinical note 04/28/11

18. MRI cervical spine 05/11/11
19. Clinical note 05/17/11
20. Clinical note 05/26/11
21. Clinical note 06/14/11
22. Interventional pain management report 06/22/11
23. Clinical note 06/30/11
24. Interventional pain management report 09/20/11 and 10/19/11
25. Clinical note 10/24/11
26. Clinical note 11/15/11
27. Electrodiagnostic studies 12/01/11
28. Clinical note 12/13/11-05/29/12
29. Radiographs with extension flexion views cervical spine 06/12/12
30. Clinical note 06/19/12
31. Prior review
32. Prior utilization review 06/28/12 and 08/01/12

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a female who has been followed for complaints of chronic pain in the cervical spine and is status post anterior cervical discectomy and fusion from C3 to C6 on 08/06/08. The first clinical note from on 01/06/10 indicated that the patient had utilized a spinal cord stimulator with no significant improvements. Medications have included Soma, Norco, Zanaflex, Mobic, and Ambien with no improvements. The patient was recommended for permanent implantation of a dorsal column stimulator which was completed on 08/03/10. The patient reported benefits from the implanted spinal cord stimulator; however, she reported that the device was not able to capture all of her left sided cervical and upper extremity symptoms. The patient's spinal cord stimulator was removed in 2011 and the patient continued to be prescribed fentanyl, Ambien, and Skelaxin as well as hydrocodone for chronic pain. MRI of the cervical spine dated 05/11/11 revealed moderately severe disc degeneration at C3-4 with 2.5mm of anterolisthesis. 1mm cord compression was noted and moderate left foraminal stenosis was present compressing the left C4 nerve root. No stenosis from C4 to C6 was present and there was moderate disc degeneration at C6-7 with a 2.5mm broad disc herniation impressing on the thecal sac. Mild foraminal stenosis was noted bilaterally. The patient was recommended for discography with CT scans on 05/17/11. Electrodiagnostic studies were recommended on 11/15/11 as discography was not approved through insurance. Electrodiagnostic studies on 12/01/11 revealed chronic left C5 radiculopathy due to nerve root irritation. Flexion and extension views of the cervical spine were completed on 06/12/12 which revealed a solid appearing anterior fusion from C4 to C6 with plate fixation. 3mm of anterolisthesis at C3-4 were noted with both flexion and extension. Clinical evaluation on 06/19/12 stated the patient continued to be recommended for reconstruction of the patient's cervical fusion. Physical examination findings were stated to be unchanged with triceps weakness present bilaterally and paresthesia in the C7 and C8 nerve root distribution. Hyperreflexia of the knee and ankle reflexes were noted bilaterally and clonus was present in

both lower extremities. Babinski's was a equivocal to the left. The request for C4-5 and C5-6 revision with hardware removal and C6-7 anterior cervical discectomy and fusion was denied by utilization review on 06/28/12 as there was no appreciable intersegmental motion noted at C6-7 and there was no documentation regarding conservative treatment to include physical therapy epidural steroid injections. The request was again denied by utilization review on 08/01/12 and there was no evidence of pseudoarthrosis from C4 to C6 and no instability present. There was no documentation regarding failure of conservative management for the disc space collapse at C6-7.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:

The request for C4 through C6 revision with hardware removal and C6-7 ACDF with instrumentation and one day length of stay is not recommended as medically necessary based on the clinical documentation provided for review and guidelines. The clinical documentation does not establish any evidence of pseudoarthrosis or failure of the fusion graft from C4 to C6. The most recent radiograph studies did not identify any hardware failure and no updated imaging studies including MRI of the cervical spine were provided for review identifying evidence of pseudoarthrosis of the fusion graft. In regards to the C6-7 level the retreating physician opines that there's clinical instability; however, flexion and extension views of the cervical spine performed in June of 2012 fail to identify any significant horizontal translation that meets clinical guidelines regarding motion segment instability. It is also noted that electrodiagnostic studies failed to identify any significant nerve root irritation at C6-7 and would also support surgical intervention. As the clinical documentation provided for review does not establish the medical need for the surgical procedures requested medical necessity is not established.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

☐ **x MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS**

☐ **x ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**

Fusion, anterior cervical	Recommended as an option in combination with anterior cervical discectomy for approved indications, although current evidence is conflicting about the benefit of fusion in general. (See Discectomy/laminectomy/laminoplasty.) Evidence is also conflicting as to whether autograft or allograft is preferable and/or what specific benefits are provided with fixation devices. Many patients have been found to have excellent outcomes while undergoing simple discectomy alone (for one- to two-level procedures), and have also been found to go on to develop spontaneous fusion after an anterior discectomy. (Bertalanffy, 1988) (Savolainen, 1998) (Donaldson, 2002) (Rosenorn, 1983) Cervical fusion for degenerative disease resulting in axial neck pain and no radiculopathy remains controversial and conservative therapy remains the choice if there is no evidence of instability. (Bambakidis, 2005) Conservative anterior

	cervical fusion techniques appear to be equally effective compared to techniques using allografts, plates or cages. (Savolainen, 1998) (Dowd, 1999) (Colorado, 2001) (Fouyas-Cochrane, 2002) (Goffin, 2003) Cervical fusion may demonstrate good results in appropriately chosen patients with cervical spondylosis and axial neck pain. (Wieser, 2007) This evidence was substantiated in a recent Cochrane review that stated that hard evidence for the need for a fusion procedure after discectomy was lacking, as outlined below: *(1) Anterior cervical discectomy compared to anterior cervical discectomy with interbody fusion with a bone graft or substitute:* Three of the six randomized controlled studies discussed in the 2004 Cochrane review found no difference between the two techniques and/or that fusion was not necessary. The Cochrane review felt there was conflicting evidence of the relative effectiveness of either procedure. Overall it was noted that patients with discectomy only had shorter hospital stays, and shorter length of operation. There was moderate evidence that pain relief after five to six weeks was higher for the patients who had discectomy with fusion. Return to work was higher early on (five weeks) in the patients with discectomy with fusion, but there was no significant difference at ten weeks. (Jacobs-*Cochrane*, 2004) (Abd-Alrahman, 1999) (Dowd, 1999) (Martins, 1976) (van den Bent, 1996) (Savolainen, 1998) One disadvantage of fusion appears to be abnormal kinematic strain on adjacent spinal levels. (Ragab, 2006) (Eck, 2002) (Matsunaga, 1999) (Katsuura, 2001) The advantage of fusion appears to be a decreased rate of kyphosis in the operated segments. (Yamamoto, 1991) (Abd-Alrahman, 1999) *(2) Fusion with autograft versus allograft:* The Cochrane review found limited evidence that the use of autograft provided better pain reduction than animal allograft. It also found that there was no difference between biocompatible osteoconductive polymer or autograft (limited evidence). (Jacobs-*Cochrane*, 2004) (McConnell, 2003) A problem with autograft is morbidity as related to the donor site including infection, prolonged drainage, hematomas, persistent pain and sensory loss. (Younger, 1989) (Sawin, 1998) (Sasso, 2005) Autograft is thought to increase fusion rates with less graft collapse. (Deutsch, 2007). See Decompression, myelopathy. *(3) Fusion with autograft with plate fixation versus allograft with plate fixation, Single level:* A recent retrospective review of patients who received allograft with plate fixation versus autograft with plate fixation at a single level found fusion rates in 100% versus 90.3% respectively. This was not statistically significant. Satisfactory outcomes were noted in all non-union patients. (Samartzis, 2005) *(4) Fusion with different types of autograft:* The Cochrane review did not find evidence that a vertebral body graft was superior to an iliac crest graft. (McGuire, 1994) *(5) Fusion with autograft versus fusion with autograft and additional instrumentation: Plate Fixation*: In single-level surgery there is limited evidence that there is any difference between the use of plates and fusion with autograft in terms of union rates. For two-level surgery, there was moderate evidence that there was more improvement in arm pain for patients treated with a plate than for those without a plate. Fusion rate is improved with plating in multi-level surgery. (Wright, 2007) See Plate fixation, cervical spine surgery. *Cage*: Donor site pain may be decreased with the use of a cage rather than a plate, but donor site pain was not presented in a standardized manner. At two years pseudoarthrosis rate has been found to be lower in the fusion group (15%) versus the cage group (44%). A six-year follow-up of the same study group revealed no significant difference in outcome variables between the two treatment groups (both groups had pain relief). In the subgroup of patients with the cage who attained fusion, the overall outcome was better than with fusion alone. Patients treated with cage instrumentation have less segmental kyphosis and better-preserved disc height. This only appears to affect outcome in a positive way in cage patients that achieve fusion (versus cage patients with pseudoarthrosis). (Poelsson, 2007) (Varuch, 2002) (Hacker 2000) See also Adjacent segment disease/degeneration (fusion). *(6) Fusion with allograft alone versus with allograft and additional instrumentation:*

	Plate Fixation: Retrospective studies indicate high levels of pseudoarthrosis rates (as high as 20% for one-level and 50% for two-level procedures) using allograft alone. In a recent comparative retrospective study examining fusion rate with plating, successful fusion was achieved in 96% of single-level cases and 91% of two-level procedures. This could be compared to a previous retrospective study by the same authors of non-plated cases that achieved successful fusion in 90% of single-level procedures and 72% of two-level procedures. (Kaiser, 2002) (Martin, 1999) See Plate fixation, cervical spine surgery. *Complications:* *Collapse of the grafted bone and loss of cervical lordosis:* collapse of grafted bone has been found to be less likely in plated groups for patients with multiple-level fusion. Plating has been found to maintain cervical lordosis in both multi-level and one-level procedures. (Troyanovich, 2002) (Herrmann, 2004) (Katsuura, 1996) The significance on outcome of kyphosis or loss of cervical lordosis in terms of prediction of clinical outcome remains under investigation. (Peolsson, 2004) (Haden, 2005) (Poelsson, 2007) (Hwang, 2007) *Pseudoarthrosis:* This is recognized as an etiology of continued cervical pain and unsatisfactory outcome. Treatment options include a revision anterior approach vs. a posterior approach. Regardless of approach, there is a high rate of continued moderate to severe pain even after solid fusion is achieved. (Kuhns, 2005) (Mummaneni, 2004) (Coric, 1997) *Anterior versus posterior fusion:* In a study based on 932,009 hospital discharges associated with cervical spine surgery, anterior fusions were shown to have a much lower rate of complications compared to posterior fusions, with the overall percent of cases with complications being 2.40% for anterior decompression, 3.44% for anterior fusion, and 10.49% for posterior fusion. (Wang, 2007) *Predictors of outcome of ACDF:* Predictors of good outcome include non-smoking, a pre-operative lower pain level, soft disc disease, disease in one level, greater segmental kyphosis pre-operatively, radicular pain without additional neck or lumbar pain, short duration of symptoms, younger age, no use of analgesics, gainful employment, higher preoperative NDI and normal ratings on biopsychosoical tests such as the Distress and Risk Assessment Method (DRAM). Predictors of poor outcomes include non-specific neck pain, psychological distress, psychosomatic problems and poor general health, litigation and workers' compensation. (Anderson, 2009) (Peolsson, 2006) (Peolsson, 2003) Patients who smoke have compromised fusion outcomes. (Peolsson, 2008) See Plate fixation, cervical spine surgery. See also Adjacent segment disease/degeneration (fusion) & Iliac crest donor-site pain treatment. *Use of Bone-morphogenetic protein (BMP):* FDA informed healthcare professionals of reports of life-threatening complications associated with recombinant human Bone Morphogenetic Protein (rhBMP) when used in the cervical spine for spinal fusion. The safety and effectiveness of rhBMP in the cervical spine have not been demonstrated, and these products are not approved for this use. These complications were associated with swelling of neck and throat tissue, which resulted in compression of the airway and/or neurological structures in the neck. (FDA MedWatch, 2008) Bone-morphogenetic protein was used in approximately 25% of all spinal fusions nationally in 2006, with use associated with more frequent complications for anterior cervical fusions. No differences were seen for lumbar, thoracic, or posterior cervical procedures, but the use of BMP in anterior cervical fusion procedures was associated with a higher rate of complication occurrence (7.09% with BMP vs 4.68% without BMP) with the primary increases seen in wound-related complications (1.22% with vs 0.65% without) and dysphagia or hoarseness (4.35% with vs 2.45% without). (Cahill-*JAMA*, 2009) For hospital LOS after admission criteria are met, see Hospital length of stay (LOS).